

---

# **TYSABRI®**

*Burt Adelman, MD*

*Executive Vice President, Development*

*Biogen Idec*

---

*7-8 March 2006*

# TYSABRI® (natalizumab) History

---

## November 2004

- ◆ TYSABRI® approved for relapsing forms of multiple sclerosis (MS)

## February 2005

- ◆ 2 probable cases of PML reported
- ◆ Voluntary suspension of TYSABRI
- ◆ Initiate comprehensive safety evaluation

## September 2005

- ◆ Safety evaluation completed
- ◆ 2-year efficacy data analyzed
- ◆ sBLA filed with FDA

# Proposed TYSABRI® Labeling

---

*TYSABRI® is indicated only for treatment of patients with relapsing forms of multiple sclerosis to delay the progression of physical disability and to reduce the frequency of clinical exacerbations.*

## Risk minimization and assessment program

- ◆ Ensure patient and physician are informed of risks and appropriate use
- ◆ Controlled distribution
- ◆ Comprehensive, proactive, pharmacovigilance

# Agenda

---

- ◆ Efficacy

Alfred Sandrock, MD, PhD (Biogen Idec)

- ◆ Safety

Michael Panzara, MD, MPH (Biogen Idec)

- ◆ Risk Management Plan

Carmen Bozic, MD (Biogen Idec)

- ◆ Clinical Perspective on Tysabri

Richard Rudick, MD

Director, The Mellen Center

Chairman, Division of Clinical Research

Cleveland Clinic Foundation

Cleveland, OH

# Biogen Idec Consultants

---

- ◆ **Richard A. Rudick, MD**

Director, The Mellen Center  
Chairman, Division of Clinical Research  
Cleveland Clinic Foundation  
Cleveland, OH

- ◆ **David Clifford, MD**

Professor of Neurology and Medicine  
Washington University School of Medicine  
Saint Louis, MO  
Member of the Independent Adjudication Committee